

REMARKS

Claims 18-20 and 22-43 are pending in this patent application. Although the Office Action identifies claim 21 as pending, Applicants note that they canceled claim 21 in their communication filed November 4, 2004. Claims 18, 20, 22, and 27 have been amended to include the phrase "capsule-shaped." Support for these amendments may be found throughout the specification, for example, on page 4, lines 12-18. Support for added claims 32-43 may be found throughout the specification, for example, in Example 1 on page 11.

Claims 22-31 stand rejected as allegedly being unpatentable over the combined teaching of U.S. Patent Nos. 5,248,310 to Barclay *et al.* (hereinafter "the Barclay patent") and 5,785,994 to Wong *et al.* (hereinafter "the Wong patent.") This rejection, however, is based upon a mistaken interpretation of Applicants' claims. Although the Office Action suggests that claims 22-31 embrace tablets having fewer than two separate drug layers (Office Action at page 3), both of the independent claims (*i.e.*, claims 22 and 27) clearly recite "a first layer formulation containing a drug ingredient" and "a second layer formulation containing a drug ingredient." Accordingly, the rejection of claims 22-31 lacks factual basis and should be withdrawn. Withdrawal of the rejection is also appropriate because the Examiner still has not identified any reason why a person of ordinary skill in the art having only the cited references before them would have produced a claimed invention. Although the Examiner asserts that a person of ordinary skill would have been motivated to modify the teachings of the cited patents (Office Action at page 3), such an assertion – even if true – is insufficient to support a rejection for alleged obviousness. Indeed, the patent laws require more than motivation to make *some* modification of the prior art; they require motivation to the modification that would have actually produced a claimed invention. *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (to establish obviousness, "there must be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant"). "In other words, the examiner must show reasons that the skilled artisan, confronted with the same problem as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

In the instant patent application, the Examiner clearly has not made the requisite showing. Initially, the Examiner asserted that “it would have been obvious ... to employ Barclay’s method of detecting different layers in the three layer osmotic dosage form of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer” (Office Action dated July 14, 2004, at page 3). Applicants, in turn, demonstrated that simply incorporating a coloring agent into the Wong dosage form, as proposed, would not have produced any claimed tablet (*i.e.*, because the Wong dosage form has only one drug-containing layer whereas the claimed tablets have at least two). Although the Examiner now alleges that adding drug layers to the Wong dosage form would have been “well within the ordinary level of a skilled artisan” (Office Action dated March 11, 2005, at page 3), the Examiner has not identified any evidence demonstrating that this further modification of the Wong dosage form would have been one that those of ordinary skill would have been motivated to make. Absent such evidence, the rejection of claims 22-31 for alleged obviousness lacks evidentiary basis and should be withdrawn. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’”).

Claims 18-20 and 22-31 stand rejected as allegedly being unpatentable over the combined teaching of the Barclay patent, the Wong patent, U.S. Patent Nos. 5,582,838 to Rork *et al.* (hereinafter “the Rork patent”) and 5,422,831 to Misra *et al.* (hereinafter “the Misra patent”). Again, however, the Examiner has failed to identify any evidence that those of ordinary skill in the art would have been motivated to modify the references’ teachings in a way that would have produced a claimed invention. Although the Examiner (employing the hindsight provided by Applicants’ disclosure) asserts that “a coloring agent can be used in determining orientation of a formulation” (Office Action at page 7), there is no evidence that a person of ordinary skill at the time of Applicants’ invention actually would have been motivated to modify the disclosed dosage forms in this manner. Even if such evidence *were* of record, the instant rejection would still lack support because the resulting dosage form would have fewer drug-containing layers than the claimed tablets. Accordingly, the Examiner would still need to come forward with evidence that those of ordinary skill would have been motivated to add drug-containing layers to the disclosed dosage forms. Since no


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such evidence is of record, the rejection for alleged obviousness is improper. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed").

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and a Notice of Allowance are respectfully requested.

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